K010505

MAR - 9 2001

This 510(k) Summary is prepared in accordance with 21 CFR 807.92.

1. BASIC INFORMATION

1.1 SUBMITTER

Name:	Brentwood Medical Technology Corp.
Address:	3300 Fujita Street Torrance, CA 90505
Contact Person:	Ruomei Zhang, PhD
Phone Number:	(310) 530-5955 x7210

Preparation Date: 02/14/2001

1.2 DEVICE NAME

The name of the device is the "Telemed 12 Lead Resting ECG Analysis Library".

The classification name is "Electrocardiograph".

The common/usual name is "Computerized Electrocardiograph".

1.3 IDENTIFICATION OF LEGALLY MARKETED DEVICE

Substantial equivalence is claimed to a legally marketed device cleared under the name, "Brentwood PC-ECG". This device was cleared through premarket notification on January 22, 1997. Its 510(k) number is K955023.

1.4 DEVICE DESCRIPTION

The *Telemed 12 Lead Resting ECG Analysis Library* is an "object library". An object library is a collection of callable functions that have been compiled (or assembled) into the native machine code of the computer on which they will execute. An application software program can be written to invoke some or all of the functions in an object library. The compiled (or assembled) application code can be "linked" to the called functions from an object library at the time the executable code image is built. An executable code image created in this manner will contain the application software code and all of the functions it invoked from the object library.

The *Telemed 12 Lead Resting ECG Analysis Library* consists of a collection of callable functions accessible by ANSI Standard C (ISO/IEC 9899) function calls to provide 12-lead resting ECG analysis capabilities. It will be compiled and delivered to ECG analysis device manufacturers by Brentwood. These manufacturers can then integrate it into the software for their ECG analysis devices.

1.5 INTENDED USE

The intended user of the *Telemed 12 Lead Resting ECG Analysis Library* user is a medical device manufacturer who will integrate it into its electrocardiograph to add 12-lead resting ECG analysis capabilities (for data captured from the human body surface) to its device. The intended user is expected to label the device for use only by or under the supervision of a trained physician. The intended user is further assumed to have

a quality system for developing and implementing software. The quality system should call for validating software, including the use of purchased software.

1.6 Comparison to Cleared Device

The *Telemed 12 Lead Resting ECG Analysis Library* code is a subset of the code for the cleared PC-ECG device. The analytical capabilities of the *Telemed 12 Lead Resting ECG Analysis Library* are identical to those of the PC-ECG. The essential differences between the *Telemed 12 Lead Resting ECG Analysis Library* and the PC-ECG are:

(1) The *Telemed 12 Lead Resting ECG Analysis Library* does not include the hardware or the user interface software of the PC-ECG.

(2) The intended user of the *Telemed 12 Lead Resting ECG Analysis Library* is the medical device integrator, whereas the intended user of the PC-ECG is the physician.

2. PERFORMANCE DATA INFORMATION

Electrocardiographs with computerized interpretation have been classified as Class III devices. No mandatory performance standards have been established for electrocardiographs with computerized interpretation, but comparison with CSE (Common Standards for Quantitative Electrocardiography) ECG database test results is encouraged.

Brentwood created a test program to analyze ECG data sets contained in the standard CSE Multilead Measurement ECG Data Bases. The test program was "linked" to analysis functions in the *Telemed 12 Lead Resting ECG Analysis Library* and used to analyze the data sets. The same test program was then "linked" to the same analysis functions from the cleared PC-ECG device and used to analyze the same data. The analytical results were compared and found to be identical. Brentwood delivers a copy of this test program to purchasers of the *Telemed 12 Lead Resting ECG Analysis Library*.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 9 2001

Ruomei Zhang, Ph.D.
Chief Technical Officer
Brentwood Medical Technology Group
3300 Fujita Street
Torrance, CA 90505

Re: K010505
Trade Name: Brentwood PC-ECG
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: February 19, 2001
Received: February 21, 2001

Dear Dr. Zhang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

510 (K) NUMBER (IF KNOWN): K010505

DEVICE NAME: TELEMED 12 LEAD RESTING ECG ANALYSIS LIBRARY

INDICATIONS FOR USE:

The Telemed 12 Lead Resting ECG Analysis Library software is a computerized ECG interpretation library. When integrated in an electrocardiograph, the ECG Analysis Library is intended to perform ECG waveform and rhythm measurements and interpretations on 12 lead resting ECG signals.

The measurements and interpretations generated by the library are recommended to be reviewed by qualified physicians. These measurements and interpretations are intended to assist the physicians in diagnosis. They are not intended as the sole basis for diagnosis.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010505